KURZPROTOKOLL
Viable

Öffentlicher Titel	Phase III Studie zu DCVAC/PCa bei metastasiertem kastrationsresistentem Prostatakarzinom
Wissenschaftl. Titel	A Randomized, Double Blind, Multicenter, Parallel-group, Phase III study to evaluate efficacy and safety of DCVAC/PCa versus Placebo in Men with metastatic Castration Resistant Prostate Cancer eligible for 1st line chemotherapy
Kurztitel	Viable
Studienart	multizentrisch, Therapiestudie, randomisiert, doppelblind, zweiarmig
Studienphase	Phase III
Erkrankung	Geschlechtsorgane: Krebserkrankungen der männlichen Geschlechtsorgane: Prostatakrebs - Zweitlinie oder höher
Ziele	- The primary objective is to show superiority of treatment with DCVAC/PCa in addition to Standard of Care (docetaxel plus prednisone) over placebo in addition to Standard of Care (docetaxel plus prednisone) in men with mCRPC as measured by overall survival (OS). - The key secondary objectives include assessments of safety, treatment group comparison with regards to radiographic progression free survival, time to prostate-specific antigen progression, time to first occurrence of skeletal related events (SRE). - Treatment group comparison for the following measures: Proportion of subjects requiring second line treatment introduction and time to second line therapy, changes in quality of life (QoL) and exploratory studies for search of potential biomarkers
Einschlusskriterien	- Male 18 years and older. - Histologically or cytologically confirmed prostate adenocarcinoma. - Presence of skeletal and/or soft-tissue/visceral/nodal metastases according to one of the following criteria: Confirmed pathological fracture related to the disease. Confirmation of distant bone and/or soft-tissue and/or visceral metastases through at least one imaging modality including CT or MRI or scintigraphy scan. (confirmation by independent review facility (IRF) required) or Positive pathology report of metastatic lesion. - Disease progression despite androgen deprivation therapy (ADT) as indicated by: PSA increase that is 25% and 2 ng/mL above the minimum PSA as reached during ADT or above the pre-treatment level, if no response was observed and which is confirmed by a second value 1 or more weeks later. OR Progression of measurable lymph nodes (short axis 15mm) or visceral lesion measurable per RECIST v1.1 criteria (confirmation by IRF required); OR Two or more new lesions appearing on bone scan/imaging compared with a privious scan (confirmation by IRF required) - Maintenance of castrate conditions: Subjects, who have not had a surgical orchiectomy, must continue with hormone therapy (GnRH/LHRH agonists or antagonists) to reach levels of serum testosterone of 1.7nmol/l (50ng/dl). The duration of the castration period must be at least 4 months before screening. - Laboratory criteria: White blood cells greater than 4,000/mm(3) (4.0 x10(9)/L). Neutrophil count greater than 1,500/mm(3) (1.5 x10(9)/L). Hemoglobin of at least 10 g/dL (100g/L). Platelet count of at least 100,000/mm(3) (100 x10(9)/L). Total bilirubin within normal limits (benign hereditary hyperbilirubinaemias, e.g. Gilbert´s syndrome are permitted). Serum alanine aminotransferase and aspartate aminotransferase, and creatinine <1.5 times the ULN. - Life expectancy of at least 6 months based on Investigator´s judgment. - Eastern Cooperative Oncology group (ECOG) Performance status 0-2. - At least 4 weeks after surgery or radiotherapy before randomization. - A minimum of 28 days beyond initiation of bisphosphonate or denosumab therapy before randomization.

	- Recovery from primary local surgical treatment, radiotherapy or orchiectomy before randomization. - Signed informed consent including patient's ability to comprehend its contents
Ausschlusskriterien	- Confirmed brain and/or leptomeningeal metastases (other visceral metastases are acceptable). - Current symptomatic spinal cord compression requiring surgery or radiation therapy. - Prior chemotherapy for prostate cancer - Patient co-morbidities: Subjects who are not indicated for chemotherapy treatment with first line Standard of Care chemotherapy (docetaxel and prednisone). HIV positive, HTLV positive. Active hepatitis B (HBV), active hepatitis C (HCV), active syphilis. Evidence of active bacterial, viral or fungal infection requiring systemic treatment. Clinically significant cardiovascular disease including: symptomatic congestive heart failure. unstable angina pectoris. serious cardiac arrhythmia requiring medication. uncontrolled hypertension. myocardial infarction or ventricular arrhythmia or stroke within a 6 month period before screening, known left ventricular ejection fraction (LVEF) <40% or serious cardiac conduction system disorders, if a pacemaker is not present. Pleural and pericardial effusion of any CTCAE grade. Peripheral neuropathy having a CTCAE grade 2. History of active malignant disease (with the exception of nonmelanoma skin tumors) in the preceding five years. Active autoimmune disease requiring treatment. History of severe forms of primary immune deficiencies. History or anaphylaxis or other serious reaction following vaccination. Known hypersensitivity to any constituent in of the DCVAC/PCa or placebo product Uncontrolled co-morbidities including, psychiatric or social conditions which, in the Investigator's opinion, would prevent participation in the trial. - Systemic corticosteroids at doses greater than 40mg hydrocortisone daily or equivalent for any reason other than treatment of prostate cancer (PCa) within 6 months before randomization. - Ongoing Systemic immunosuppressive therapy for any reason. - Treatment with anti-androgens, inhibitors of adrenal-produced androgens or other hormonal tumor-focused treatment performed on the day of randomization (except for GnRH/LHRH agonists or antagonists), to exclude possible anti-androgen withdrawal response. This criterion does not apply to subjects, who have never responded to anti-androgen treatment as there is no risk of antiandrogen withdrawal response. - Treatment with immunotherapy against PCa within 6 months before randomization. - Treatment with radiopharmaceutical within 8 weeks before randomization. - Participation in a clinical trial using experimental therapy within 4 weeks before randomization. - Participation in a clinical trial using immunological experimental therapy (e.g. monoclonal antibodies, cytokines or active cellular immunotherapies) within 6 months before randomization. - Refusal to sign the informed consent
Alter	18 Jahre und älter
Fallzahl	1170
Sponsor	SOTIO a.s.
Registrierung in anderen Studienregistern	EudraCT 2012-002814-38